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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/635,865	08/06/2003	Andrew David Carlson	X-11408C	8787

25885 7590 05/13/2005

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EXAMINER	
KOSSON, ROSANNE	
ART UNIT	**PAPER NUMBER**
1651	

DATE MAILED: 05/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/635,865	CARLSON ET AL.	
	Examiner	Art Unit	
	Rosanne Kosson	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *13-15 and 17-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *13-15 and 17-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicants' response filed on April 25, 2005 has been received. Claims 13 and 17 have been amended. Claim 16 has been canceled. Claims 18-28 have been added. Accordingly, claims 13-15 and 17-28 are pending and are examined on the merits herewith.

The text of those sections of Title 35, U.S. code, not included in this action can be found in a prior office action.

Claim Rejections - 35 USC § 112

In view of Applicants' amendment to claim 13, the rejection under 35 USC §112, first paragraph, is withdrawn.

Claim Rejections - 35 USC § 103

Claims 13-15 and 17 are again rejected, and claims 18-28 are rejected, under 35 U.S.C. 103(a) as being unpatentable over Hirahara (US 5,084,273) in view of Mochida Pharmaceutical Co. Ltd. (JP 08-301786, see enclosed English machine translation). This rejection was discussed in a previous Office action.

Applicants assert that the claimed invention is patentable over the cited art, because the cited art does not specifically disclose a composition with a ratio of 1 part of activated Protein C (aPC) to 5-7 parts of bulking agent. At this ratio of aPC:bulking agent, a mechanism by which aPC is degraded (presumably in the reconstituted

composition after injection into the circulatory system of a subject), is minimized. Applicants additionally assert that the compositions in the cited art also comprise heparin or heparin and ATIII.

In reply, the cited art does not specifically disclose a ratio of 1 part of aPC to 5-7 parts of bulking agent. But, Applicants specification does not disclose that this ratio is associated with any particular result or unexpected finding. The specification compares the degradation of compositions containing 1 part of aPC to 5-7 parts of bulking agent in which the bulking agent is one of compounds recited in claim 14. A couple of other bulking agents are also tested, and comparisons are made to a composition containing no bulking agent. But different ratios of aPC:bulking agent are not tested. Thus, Applicants have not demonstrated that this preferred ratio imparts stability to solutions of aPC. Consequently, the claims are not commensurate in scope with the disclosure. Applicants may, however, present such data for consideration.

Applicants note that Hirahara does not discuss the degradative mechanism involving des(1-9)aPC and des(1-10)aPC. But, this mechanism is not a limitation recited in the claims, i.e., a composition formulated to minimize autodegradation upon reconstitution or rehydration is not claimed.

Further, regarding the presence of heparin in a composition comprising aPC and a bulking agent, the comprising language in the claims does not exclude the presence of additional components, such as heparin. Regarding the presence of a stabilizing agent, Mochida discloses that aPC and a bulking agent may be formulated according to any well-known pharmaceutical manufacturing method. The resulting composition may

contain one or more of a number of other agents (see paragraph 15). Again, the comprising language in the claims does not exclude the presence of additional components.

With respect to Applicants' comments on the dosages in Hirahara and in the claimed invention, Applicants note Hirahara's disclosure of 5 mg to 1 g of protein per dose for a 60 kg adult and an aPC concentration in the preparations of 2 to 20 µg/ml. In the Examples, Hirahara discloses 10 ml preparations containing 1.5 mg of aPC. Thus, 1.5 mg may also be a dose. Claim 18 recites administering 0.01 to 0.05 mg/kg/hr. A 60 kg person would receive 0.6 to 3 mg/hr. If the infusion of claim 18 is administered for one to two and a half hours (at a concentration of 1.5 to 0.6 mg/hr), the person would receive an amount of aPC equivalent to that in one 10 ml vial of Hirahara. Consequently, the dosing regime of claim 18 does not distinguish the claimed invention over Hirahara.

In view of the foregoing, the rejection of record is maintained. No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rosanne Kosson whose telephone number is 571-272-2923. The examiner can normally be reached on Monday-Friday, 8:30-6:00, with alternate Mondays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rosanne Kosson
Examiner
Art Unit 1651

rk
2005-03-24

ROBERT A. WAX
PRIMARY EXAMINER
Art Unit 1653